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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Randy Westlund

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EXAMINER

SCHAETZLE, KENNEDY

ART UNIT

PAPER NUMBER

3766

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/617,881	Applicant(s) WESTLUND ET AL.	
	Examiner Kennedy J. Schaetzle	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-56 and 58-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 54-56 and 58-60 is/are allowed.
- 6) ☒ Claim(s) 40-53, 61 and 62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 40-64 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-58 of U.S. Patent No. 6,901,288.

Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 40 of the present invention is for the most part, merely broader in scope than claims 1-58 of the patent. Once the applicant has received a patent for a more specific embodiment, he is not entitled to a patent for the generic or broader invention (*In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993)). While it is noted that claim 40 requires an electrode to be disposed proximate the distal end, those of ordinary skill in the art recognizing the claimed lead of the '288 patent to

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be a lead "...capable of pacing the heart..." and comprising a conductive member extending through the lead body, would have considered the use of such an electrode in order to supply the pacing pulse to the heart as totally obvious and necessary for proper operation. Regarding the open and closed state of the seal, given that the seal may be ring shaped (claim 3) and that the seal coupling element includes a passage coaxial with the lumen to allow implantation of the lead over a guidewire, any seal attempting to limit fluid entry into the lead body must therefore have an open and closed state where the open state allows guidewire passage and the closed state prevents fluid entry. In addition, a seal coupling element with a distal portion of greater diameter than a proximal portion diameter inherently creates a shoulder. In any event, given the suggestion to create a seal coupling element with the different recited distal and proximal diameters, one would consider the use of a shoulder-shaped housing (i.e., a housing with two distinct diameters) to be an obvious choice (it is also noted that patented claim 9 recites use of a shoulder-shaped seal coupling element).

3. Regarding method claims 61-64, the examiner has not required a restriction in the present case because the inventions are not considered to be patentably distinct. Performance of the method would necessarily require apparatus of the type claimed in the '288 patent.

4. Claims 47-53 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-58 of U.S. Patent No. 6,901,288 in view of Bartig (Pat. No. 6,408,213) or Sommer et al. (Pat. No. 6,192,280).

5. The application of Bartig and Sommer et al. to claims 47-53 parallel the §103 rejection of like claims below.

Claim Rejections - 35 USC § 102/103

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 47, 48, 51, 52 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over De Lurgio et al. (Pat. No. 6,714,823).

Regarding claim 47, a *cusps* as defined by Merriam Webster encompasses a point, an apex, a point of transition, a fold or a flap. In the broadest reasonable sense the closable seal shown by De Lurgio et al. could therefore be described as a *cusps* since it clearly represents at least a point or a point of transition. One could also consider the seal of De Lurgio et al. to fold over itself when in an expanded state, or represent a flap in the sense that the inner circumference is free to move while the outer circumference is attached to the lumen of the lead.

In any event, those of ordinary skill and common sense in the art recognizing the suggestion by De Lurgio et al. to provide a closable seal defining a closable seal lumen for receiving a guidewire, would have considered the exact means used to accomplish this goal to be a matter of obvious design. One would expect any known seal allowing the requisite passage of a guidewire and adequate sealing to prevent fluid leakage to be suitable to both the present invention and the De Lurgio et al. invention (attention is invited to col. 4, lines 56-67 of Bartig Pat. No. 6,408,213 for its disclosure of a *cusps* seal in a medical lead). The applicants further give no criticality to the use of any one particular seal over another –merely stating that they use a seal that is allegedly different than the seal of De Lurgio et al.. Patentability does not hinge on whether there

is a mere difference between the invention and the prior art; the difference must be novel and unobvious. The applicants proffer no evidence that their seal is patentably distinct over the seal of De Lurgio et al.. Given that the crux of the invention is to prevent fluid from entering the lead while still allowing the use of a guidewire for placement, and given that the system of De Lurgio et al. permits this functioning to be realized, to merely substitute one particular suitable sealing arrangement for another to produce predictable results would have been considered obvious to those of ordinary skill in the medical lead arts.

Claim Rejections - 35 USC § 103

10. Claims 47-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over De Lurgio et al. in view of Bartig (Pat. No. 6,408,213) or Sommer et al. (Pat. No. 6,192,280).

De Lurgio et al. do not explicitly refer to the use of a closeable seal that includes at least one cusp. Bartig (with similar arguments applying to Sommer et al. who show at least one cusp 36c in Fig. 6), however, discloses a medical lead wherein a closeable seal can either comprise a disk with an orifice sized to allow a guidewire to pass through it such as disclosed by De Lurgio et al., or a self-sealing flap (see col. 4, lines 56-67). A flap is considered to be a cusp by definition as discussed above. The courts have recognized that the simple substitution of one known element for another to obtain predictable results can be a rationale for arriving at a conclusion of obviousness. Clearly any seal that prevents fluid leakage while permitting a guidewire to pass would have been considered suitable to the invention by those of ordinary skill and common

sense in the art. One would expect such a seal to work equally well because its function is the same as demanded by De Lurgio et al.. To therefore include a seal with a cusp or flap would have been considered an obvious matter of design.

Regarding claims directed to the use of seals including bi-cusp, tri-cusp and quad-cusp arrangements, one would expect any number of flaps or cusps to be suitable to the invention provided they enabled passage of a guidewire while preventing fluid ingress. The applicants give no criticality in the number of flaps used. Artisans familiar with the heart are well-aware of bi-cusp and tri-cusp seals such as the mitral and tricuspid valves. Common sense would have lead those of ordinary skill in the art to at least try to mimic these natural seals (or similarly designed prosthetic seals specifically constructed for use in the heart) since they are ideally suited to prevent fluid backup while allowing elongated structures such as pacer leads to pass through.

11. Claims 61 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over De Lurgio et al..

De Lurgio et al. do not disclose at least a portion of the seal formed from an expandable matrix material. De Lurgio et al. disclose that the preferred seal material is flexible, nonconductive, abrasion-resistant and of high lubricity (see the text abridging cols. 6 and 7), and list silastic rubber and siloxane as possible suitable candidate materials. The present invention discloses that silicone rubber, hydrogels and biocompatible elastomers are suitable materials (see page 8, 2nd full paragraph). At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to utilize an expandable matrix material because

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the applicants have not disclosed that such material provides an advantage, is used for a particular purpose, or solves a stated problem compared to equally suitable materials such as rubbers and elastomers. One of ordinary skill in the art, furthermore, would have expected the applicants' invention to perform equally well with silastic rubber or siloxane because these materials are biocompatible and elastic. The applicants disclosure on page 8 of the present specification that silicone rubber and biocompatible elastomers may be used to form the seal lend further support to the assertion that the invention would work equally well with materials other than expandable matrix materials.

Allowable Subject Matter

12. Claims 54-56 and 58-60 are allowed.

Response to Arguments

13. Applicant's arguments with respect to the rejected claims have been considered but are moot in view of the new ground(s) of rejection.

14. Regarding the obviousness-type double patenting rejection, it is not enough that there is a difference between claims of the present invention and claims of the '288 patent, the difference must be patentably distinct. A seal designed to prevent fluid from entering the lumen while allowing a guidewire to pass through the lumen of the seal coupling element must have an open state to allow the guidewire to pass and a closed state to prevent fluid ingress.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy J. Schaetzle whose telephone number is 571 272-4954. The examiner can normally be reached on M-F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on M-F at 571 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kennedy J. Schaetzle/
Primary Examiner, Art Unit 3766

KJS
July 4, 2008